



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/566,333

01/27/2006

Gilad Lavi

S2082/20004

4212

3000 7590 07/23/2008
CAESAR, RIVISE, BERNSTEIN,
COHEN & POKOTILOW, LTD.
11TH FLOOR, SEVEN PENN CENTER
1635 MARKET STREET
PHILADELPHIA, PA 19103-2212

EXAMINER

ANDERSON, MICHAEL J

ART UNIT

PAPER NUMBER

3767

NOTIFICATION DATE

DELIVERY MODE

07/23/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@crbcp.com

Office Action Summary	Application No. 10/566,333	Applicant(s) LAVI ET AL.	
	Examiner MICHAEL J. ANDERSON	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21, 31-34, 60 and 61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 21, 31, 60 and 61 recite the limitation "protrusions" in reference to previous claims that do not disclose protrusions. There is insufficient antecedent basis for this limitation in the claim.

Claim 32 recites the limitation "the barrel scale" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claims 33 and 34 depend from claim 32.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-31, 35-42, 44-65 and 69-70 are rejected under 35 U.S.C. 102(b) as being anticipated by Bitdinger (US Patent No. 5,478,316).

With regard to claims 1, 9, 38, 44, and 45 Bitdinger discloses (abstract; figures 1-19) an injection device comprising: a housing (12) having a proximate end and a distal

Art Unit: 3767

end, the distal end (16) having an opening therein; a shield (28) slideably coupled to the housing at said distal end thereof; a cartridge barrel (30) within the housing, the cartridge barrel having proximate and distal ends; a needle cannula (38) fixed to the distal end of the cartridge barrel, or attachment means for fixing a needle cannula to the distal end, said needle cannula being disposed within said shield prior to activation of said device (figures 2-5); a stopper (24) within the cartridge barrel; a driver (32, 46) coupled to the stopper; a spring (40, 56) coupled between the housing and the driver; a driver trigger (66) for retaining the driver fixed to the housing and in which state the spring is in a compressed state, the trigger being actuatable in use to release the driver from the housing thereby allowing the spring to urge the driver through the housing and with it the stopper through the cartridge barrel; and a release mechanism for releasing the spring from the driver at some point on its travel through the housing, whereupon the spring engages the shield and automatically urges the shield away from the housing so as to cover the needle cannula (column 4, lines 9-65).

With regard to claim 2 Bitdinger discloses (abstract; figures 1-19) an injection device according to claim 1 and comprising means for allowing the driver to drive the cartridge barrel through the housing following activation of said driver trigger and prior to movement of the stopper through the cartridge barrel, thereby urging the needle cannula outward relative to the housing and shield (column 4, lines 9-65).

With regard to claim 3 Bitdinger discloses (abstract; figures 1-19) an injection device according to claim 1, the driver trigger being coupled to said shield, wherein

movement of the shield inwardly with respect to the housing activates the trigger (column 4, lines 9-65).

With regard to claim 4 Bitdinger discloses (abstract; figures 1-19) an injection device according to claim 3, wherein said trigger is actuated prior to the emergence of the needle cannula from the shield (column 4, lines 9-65).

With regard to claim 5 Bitdinger discloses (abstract; figures 1-19) an injection device according to claim 3, wherein said trigger is actuated subsequent to emergence of the needle cannula from the shield (column 4, lines 9-65).

With regard to claim 6 Bitdinger discloses (abstract; figures 1-19) an injection device according to claim 1, wherein the driver trigger comprises a resilient member on one of the driver and the housing and a complimentary engaging member on the other of the driver and housing, and wherein said trigger is actuated by a force of sufficient magnitude applied between the driver and the housing (columns 3 and 4).

With regard to claim 7 Bitdinger discloses (abstract; figures 1-19) an injection device according to claim 1, wherein said driver trigger comprises a resilient member on one of the driver and the housing and a complimentary engaging member on the other of the driver and housing, and wherein said trigger is arranged to receive a trigger release member of the shield following movement of the shield into the housing (columns 3-5).

With regard to claim 8 Bitdinger discloses (abstract; figures 1-19) an injection device according to claim 1, wherein said housing is generally cylindrical in shape and the spring (40, figure 3) and cartridge barrel are located coaxially within the housing.

With regard to claim 9 Bitdinger discloses (abstract; figures 1-19) an automatic injector for delivering a fluid, comprising: a housing, said housing having a proximate end and a distal end; a shield interfaced with the housing at a housing distal end and wherein said housing and said shield are arranged in a sliding relationship forming an enclosure; a driver positioned within said enclosure and engaged to the housing and adapted to disengage from the housing upon activation of said shield; a cartridge positioned within said enclosure, and wherein said cartridge has a needle extending towards said shield, said needle being disposed within said shield prior to activation of said shield; a barrel, said barrel arranged to contain a stopper and the fluid therein and wherein the fluid is in communication with said needle; said driver slidably located within said housing for forcing the fluid through said needle upon activation of said injector; and said driver further adapted to be biased by a driving unit, said driving unit causing said driver to slide towards said housing distal end and move a stopper through said barrel to push the fluid through said needle for delivery into an injection site; and wherein said shield is automatically deployed following fluid delivery (see claim 1).

With regard to claim 10 Bitdinger discloses (abstract; figures 1-19) the automatic injector of claim 9, wherein said shield displacement and driver disengagement require a substantial force over a short travel distance (column 4).

With regard to claim 11 Bitdinger discloses (abstract; figures 1-19) the automatic injector of claim 10, wherein said shield displacement and driver disengagement force (column 4) required from the user is about 1 **k_{gf}**.

With regard to claim 12 Bitdinger discloses (abstract; figures 1-19) the automatic injector of claim 10, wherein the driver disengagement from the housing takes place over the initial part of the shield travel (column 4).

With regard to claim 13 Bitdinger discloses (abstract; figures 1-19) the automatic injector of claim 9 wherein said force exerted by the automatic injector on the shield is minimal during delivery.

With regard to claim 14 Bitdinger discloses (abstract; figures 1-19) the automatic injector of claim 9, further comprising an automatic retracting mechanism that automatically retracts said shield after the completion of injection (columns 4 and 5).

With regard to claim 15 Bitdinger discloses (abstract; figures 1-19) the automatic injector of claim 14, wherein said driver is arranged to allow the driving unit to force the retraction of the shield and shielding the needle at the end of delivery (columns 4 and 5).

With regard to claim 16 Bitdinger discloses (abstract; figures 1-19) the automatic injector of claim 9 wherein said housing includes a set of supports extending longitudinally from a proximate end of the housing, said supports adapted to abut said cartridge barrel and prevent axial movement of said cartridge before, during and after operation of the automatic injector.

With regard to claim 17 Bitdinger discloses (abstract; figures 1-19) the automatic injector of claim 9, wherein said driver includes a set of cartridge barrel supports extending longitudinally and which slide on the external surface of the barrel during injection.

With regard to claim 18 Bitdinger discloses (abstract; figures 1-19) the automatic injector of claim 17, wherein said cartridge barrel supports are adapted to detect the end of barrel and release the driving unit.

With regard to claim 19 Bitdinger discloses (abstract; figures 1-19) the automatic injector of claim 9 wherein said driving unit is a spring arranged to bias said driver to push said stopper into said barrel and then move said shield into a needle shielding position (figures 6 and 7).

With regard to claim 20 Bitdinger discloses (abstract; figures 1-19) the automatic injector of claim 19, wherein the released spring provides the user with a tactile and audible feedback of the end of delivery (column 4, line 21).

With regard to claim 21 Bitdinger discloses (abstract; figures 1-19) the he automatic injector of claim 9 wherein said protrusions releasably engage said housing (66, 70).

With regard to claim 22 Bitdinger discloses (abstract; figures 1-19) the automatic injector of claim 9 wherein said housing has an opening at said proximate end, said injector further comprising a rod (46) extending through said opening and arranged to push said stopper into said barrel before activation of said injector.

With regard to claim 23 Bitdinger discloses (abstract; figures 1-19) the automatic injector of claim 22, wherein said rod has a smooth surface for axial movement in relation to said housing opening.

With regard to claim 24 Bitdinger discloses (abstract; figures 1-19) the automatic injector of claim 22, wherein said rod has a threaded section for rotational axial movement in relation to said housing opening (column 5, line 60 to column 6, line 7).

With regard to claim 25 Bitdinger discloses (abstract; figures 1-19) the automatic injector of claim 23, wherein said rod has a serrated edge (52) for incremental axial movement in relation to said housing opening.

With regard to claim 26 Bitdinger discloses (abstract; figures 1-19) the automatic injector of claim 9 further comprising a safety tab (66) removably engaged with said enclosure, said tab arranged to prevent activation of said injector when said tab is engaged with said enclosure.

With regard to claim 27 Bitdinger discloses (abstract; figures 1-19) the automatic injector of claim 9 wherein said cartridge comprises a barrel having a closed distal end and a proximate end, said needle having a distal end for exposure to the injection site and a proximate end arranged to penetrate said closed distal end of the cartridge and providing fluid communication between the distal end of the needle and the interior of the cartridge, said proximate end of said cartridge arranged to accept said driver.

With regard to claim 28 Bitdinger discloses (abstract; figures 1-19) the automatic injector of claim 9 wherein said shield has an inner circumferential wall and an outer circumferential wall, said housing having an inner circumferential wall and an outer circumferential wall, said housing and said shield arranged in a sliding relationship, said housing and said automatic injector having an arrangement for latching the shield in the needle shielding position.

With regard to claim 29 Bitdinger discloses (abstract; figures 1-19) the automatic injector of claim 28, wherein said enclosure further comprises a leaf spring at said distal end of the enclosure, said leaf spring arranged to abut said driving unit after retraction of said shield and prevent potential re-exposure of said needle.

With regard to claim 30 Bitdinger discloses (abstract; figures 1-19) the automatic injector of claim 28, wherein said enclosure further comprises pins and pattern (66's) arranged at said distal end of enclosure, said pins and pattern arranged to interact during the use of the automatic injector and prevent potential re-exposure of said needle.

With regard to claim 31 Bitdinger discloses (abstract; figures 1-19) the automatic injector of claim 21, wherein said activation of said injector occurs after application of the axial pressure on the housing of the injector; said shield moving to expose the needle and to separate said protrusions from said housing to allow axial movement of said driver and said stopper in said barrel, holding said injector at the injection site for the duration of the injection.

With regard to claim 35 Bitdinger discloses (abstract; figures 1-19) the automatic injector of claim 28, wherein said shield outer circumferential wall are arranged in a sliding relationship with said housing inner circumferential wall.

With regard to claim 36 Bitdinger discloses (abstract; figures 1-19) the automatic injector of claim 28, wherein said shield inner circumferential wall are arranged in a sliding relationship with said housing outer circumferential wall.

With regard to claim 37 Bitdinger discloses (abstract; figures 1-19) the automatic injector of claim 33, wherein said housing further has an extended section enveloping said shield and providing improved holding ability for the user.

With regard to claim 38 Bitdinger discloses (abstract; figures 1-19) the automatic injector for delivering a fluid, comprising: a housing, said housing having a proximate end and a distal end; a shield interfaced with the housing at a housing distal end, wherein said housing and said shield are arranged in a sliding relationship forming an enclosure; a driver positioned within said enclosure and engaged to the housing and adapted to disengage from the housing upon activation of the shield; a cartridge positioned within said enclosure, said cartridge having a needle extending towards said shield, said needle being disposed within said shield prior to activation of said injector; a barrel, said barrel arranged to contain a stopper and the fluid therein, the fluid in communication with said needle; a rod arranged to communicate with said stopper before the activation, said rod arranged to move said stopper for titration before the activation and to automatically separate from said stopper upon activation; said driver being slidably located within said housing for forcing the fluid through said needle upon activation of said injector; said driver further adapted to be biased by a driving unit and said driving unit causing said driver to slide towards said distal end and move said stopper through said barrel to push the fluid through said needle for delivery into an injection site; and wherein said shield is automatically deployed following fluid delivery (see claim 1).

With regard to claim 39 Bitdinger discloses (abstract; figures 1-19) the automatic injector of claim 38, wherein said housing has an aperture on the proximate end, said rod arranged to extend into said aperture during communication with said stopper and move said stopper during titration.

With regard to claim 40 Bitdinger discloses (abstract; figures 1-19) the automatic injector of claim 39, wherein said rod has a section for axial movement in relation to said housing opening.

With regard to claim 41 Bitdinger discloses (abstract; figures 1-19) the automatic injector of claim 39, wherein said rod has a threaded section for rotational axial movement in relation to said housing opening.

With regard to claim 42 Bitdinger discloses (abstract; figures 1-19) the automatic injector of claim 39, wherein said rod has a serrated edge for incremental axial movement in relation to said housing opening.

With regard to claim 44 Bitdinger discloses (abstract; figures 1-19) the injector for automatically injecting and delivering fluids into a living being, said injector comprising: a housing having a first proximal end and a first distal end that is open; a cartridge having a barrel containing a fluid, said cartridge further comprising a displaceable stopper at a second proximal end and a needle at a second distal end, said cartridge being fixed within said housing; a driver engaged within said housing for driving said stopper to dispense the fluid from said barrel and through said needle when disengaged from said housing; a needle shield being in sliding engagement with said first distal end of said housing and comprising an opening for permitting said needle to pass

therethrough, said needle being disposed within said needle shield prior to activation of said injector; and a single spring, engaged with said driver, that is released by a user force, said single spring displacing said driver for automatically injecting and delivering the fluid into the living being and for automatically acting against the needle shield to remove the needle from the living being while automatically concealing the needle within said shield once the fluid delivery is complete (see claim 1).

With regard to claim 45 Bitdinger discloses (abstract; figures 1-19) an automatic injector for delivering a fluid, comprising: a housing, said housing having a proximate end and a distal end; a shield interfaced with the housing; said housing and said shield arranged in a sliding relationship forming an enclosure; said driver positioned within said enclosure; a cartridge positioned within said enclosure, said cartridge having a needle extending towards said shield, said needle being disposed within said shield prior to activation of said injector; a cartridge barrel, said barrel arranged to contain a stopper and the fluid therein, the fluid in communication with said needle, said driver slidably located within said housing for moving the needle forward to insert it into tissue and for forcing the fluid through said needle upon activation of said injector; a driver attached to the housing and adapted to disengage from the housing upon activation of the injector; said driver further adapted to be biased by a driving unit and said driving unit causing said driver to slide towards said distal end to forward the cartridge with the needle and move said stopper through said barrel to push the fluid through said needle and deliver fluid into an injection site; and wherein said shield is automatically deployed following fluid delivery (see claim 1).

With regard to claim 46 Bitdinger discloses (abstract; figures 1-19) the automatic injector of claim 45, wherein said shield displacement requires a substantial force over a short travel distance.

With regard to claim 47 Bitdinger discloses (abstract; figures 1-19) the automatic injector of claim 46, wherein the shield displacement force is sufficient to ensure rapid housing and shield disengagement.

With regard to claim 48 Bitdinger discloses (abstract; figures 1-19) the automatic injector of claim 45, wherein said the force (F) exerted by the shield of the automatic injector on the tissue is minimal during delivery.

With regard to claim 49 Bitdinger discloses (abstract; figures 1-19) the automatic injector of claim 48, wherein the shield and the housing have latches maintaining the relative housing to shield position during delivery.

With regard to claim 50 Bitdinger discloses (abstract; figures 1-19) the automatic injector of claim 45, wherein the force exerted by the automatic injector moves the cartridge toward the distal end of the automatic injector to insert the needle into tissue and deliver the drug.

With regard to claim 51 Bitdinger discloses (abstract; figures 1-19) the automatic injector of claim 45, further comprising a mechanism that automatically retracts said shield and shields the needle after the completion of injection.

With regard to claim 52 Bitdinger discloses (abstract; figures 1-19) the automatic injector of claim 51, wherein said driver is arranged to allow the driving unit to force the shield in the distal direction and shield the needle at the end of delivery.

With regard to claim 53 Bitdinger discloses (abstract; figures 1-19) the automatic injector of claim 45, wherein said housing includes a support extending longitudinally from said proximate end of the housing, said support adapted to abut said cartridge barrel and prevent axial movement of said cartridge before use.

With regard to claim 54 Bitdinger discloses (abstract; figures 1-19) the automatic injector of claim 45, wherein said shield includes protrusions extending longitudinally from the distal end and limiting cartridge motion toward the distal end of the injector after activation.

With regard to claim 55 Bitdinger discloses (abstract; figures 1-19) the automatic injector of claim 45, wherein said driver includes a set of cartridge barrel supports extending longitudinally and sliding on the external surface of the barrel during injection.

With regard to claim 56 Bitdinger discloses (abstract; figures 1-19) the automatic injector of claim 55, wherein said cartridge barrel supports are adapted to detect the end of barrel and release the shield.

With regard to claim 57 Bitdinger discloses (abstract; figures 1-19) the automatic injector of claim 55, wherein said driver has protrusions supporting the barrel from axial motion toward the distal end of the automatic injector after injection completion.

With regard to claim 58 Bitdinger discloses (abstract; figures 1-19) the automatic injector of claim 45, wherein said driving unit is a spring arranged to bias said driver to push said cartridge to insert the needle into tissue, to push said stopper into said barrel and then move said shield into needle shielding position.

With regard to claim 59 Bitdinger discloses (abstract; figures 1-19) the automatic injector of claim 58, wherein said released spring provides the user with a tactile and audible feedback of the end of delivery.

With regard to claim 60 Bitdinger discloses (abstract; figures 1-19) the automatic injector of claim 45, wherein said driver protrusions releasably engage said housing.

With regard to claim 61 Bitdinger discloses (abstract; figures 1-19) the automatic injector of claim 60, said activation of said injector occurs after application of an axial force on the shield of the injector; said shield moving to separate said driver protrusions from said housing to allow and said holding said injector at the injection site for the duration of the injection.

With regard to claim 62 Bitdinger discloses (abstract; figures 1-19) the automatic injector of claim 45, wherein said cartridge comprises a barrel having a closed distal end and a proximate end, said needle having a distal end for exposure to the injection site and a proximate end arranged to penetrate said closed distal end of the cartridge and provide fluid communication between the distal end of the needle and the interior of the cartridge, said proximate end of said cartridge arranged to accept said driver.

With regard to claim 63 Bitdinger discloses (abstract; figures 1-19) the automatic injector of claim 45, wherein said shield has an inner circumferential wall and an outer circumferential wall, said housing having an inner circumferential wall and an outer circumferential wall, said housing and said shield arranged in a sliding relationship, and said automatic injector having arrangements for latching the shield to the housing.

With regard to claim 64 Bitdinger discloses (abstract; figures 1-19) the automatic injector of claim 63, wherein said shield further comprises a hook at said distal end and the housing comprising matching windows at distal end of said housing for engaging the shield and housing in storage and delivery positions.

With regard to claim 65 Bitdinger discloses (abstract; figures 1-19) the automatic injector of claim 63, wherein said shield further comprises a leaf spring said leaf spring arranged to abut said driving unit after retraction of said shield and prevent potential re-exposure of said needle.

With regard to claim 66 Bitdinger discloses (abstract; figures 1-19) the automatic injector of claim 45, further comprising a safety tab remove- ably engaged with said enclosure, said tab arranged to prevent activation of said injector when said tab is engaged with said enclosure.

With regard to claim 69 Bitdinger discloses (abstract; figures 1-19) the automatic injector of claim 45, wherein said injector is equipped with a safety tab said shield proximate displacement requires the removal of the safety tab.

With regard to claim 70 Bitdinger discloses (abstract; figures 1-19) the automatic injector of claim 45, wherein said injector is equipped with a needle cover (16) assembly cup, said shield displacement requires the removal of the cup together with the needle cover assembly.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 32-34, 43 and 67-68 are rejected under 35 U.S.C. 103(a) as being as being unpatentable over Bitdinger in view of Marshall (US patent No. 5,599,309).

With regard to claims 32-34, 43 and 67-68 Bitdinger discloses (abstract; figures 1-19) the automatic injector of claim 28, However, Bitdinger does not disclose wherein said housing and shield further include a window arranged to allow viewing of the barrel, the barrel scale and the fluid in the barrel. Marshall (abstract, figure 1, and 6-9) discloses a set of supports, injector rods, safety tabs, injector cartridge and viewing window. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the injection syringe of Bitdinger se as disclosed by Marshall to make the safety shield injection syringe automated with transparent parts for seeing the medicine dose available.

Previous rejections

Claims 1, 9, 38, 44, and 45 are rejected under 35 U.S.C. 103(a) as being as being unpatentable over Chevallier (US patent publication No. 2002/0193746 A1)

(Chevallier) and/or Jansen (US patent 6,319,233) (Jansen) in view of Gilbert (US patent No.7,097,634) (Gilbert).

With regard to claim 1, 9, 38, 44, and 45 Chevallier discloses (abstract; figures 1-8) an injection device (figures 1) comprising: a housing (10) having a proximate end and a distal end, the distal end having an opening therein; a shield (16, 18) slideably coupled to the housing at said distal end thereof; a cartridge barrel (A) within the housing, the cartridge barrel having proximate and distal ends; a needle (14) cannula fixed to the distal end of the cartridge barrel, or attachment means for fixing a needle cannula to the distal end; a stopper (12) within the cartridge barrel; a driver (12) coupled to the stopper; a spring (30, 32, 22) coupled between the housing and the driver; a driver trigger (12, abstract) for retaining the driver fixed to the housing and in which state the spring is in a compressed state, the trigger being actuable in use to release the driver from the housing thereby allowing the spring to urge the driver through the housing and with it the stopper through the cartridge barrel; and a release mechanism for releasing the spring from the driver at some point on its travel through the housing, whereupon the spring engages the shield and urges the shield away from the housing so as to cover the needle cannula (abstract). Chevallier does not disclose the cannula being disposed within said shield prior to activation of said device. Gilbert discloses (column 1, lines 20-50) the cannula being disposed within said shield prior to activation of said device. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the injection syringe of Chevallier as disclosed by Gilbert to make the safety shield protection prior to injection.

Furthermore, with regard to claim 1, 9, 38, 44, and 45 Jansen discloses (abstract; figures 1-19) an injection device (10) comprising: a housing (26) having a proximate end and a distal end, the distal end having an opening therein; a shield (28) slideably coupled to the housing at said distal end thereof; a cartridge barrel (16) within the housing, the cartridge barrel having proximate and distal ends; a needle (18) cannula fixed to the distal end of the cartridge barrel, or attachment means for fixing a needle cannula to the distal end; a stopper (20) within the cartridge barrel; a driver (22) coupled to the stopper; a spring (30) coupled between the housing and the driver; a driver trigger (48, 58) for retaining the driver fixed to the housing and in which state the spring is in a compressed state, the trigger being actuable in use to release the driver from the housing thereby allowing the spring to urge the driver through the housing and with it the stopper through the cartridge barrel; and a release mechanism for releasing the spring from the driver at some point on its travel through the housing, whereupon the spring engages the shield and urges the shield away from the housing so as to cover the needle cannula (columns 2, 4, and 6). Jansen does not disclose the cannula being disposed within said shield prior to activation of said device. Gilbert discloses (column 1, lines 20-50) the cannula being disposed within said shield prior to activation of said device. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the injection syringe of Jansen as disclosed by Gilbert to make the safety shield protection prior to injection.

Claims 2, 3-7, 8, 10-15, 35-37, 46-48, 61, 63-64, 70 19-21, 50-52, and 58-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chevallier (US patent

publication No. 2002/0193746 A1) (Chevallier) and/or Jansen (US patent 6,319,233) (Jansen) in view of Lavi (US patent publication 2003/0105430) (Lavi) and/or Marshall (US patent No. 5,599,309) (Marshall) and further in view of Gilbert (US patent No. 7,097,634) (Gilbert).

With regard to claim 2, 8, 19-21, 50-52, and 58-59, Chevallier and Gilbert disclose an injection device according to claim 1 however, Chevallier may not disclose a means for allowing the driver to drive the cartridge barrel through the housing following activation of said driver trigger and prior to movement of the stopper through the cartridge barrel, thereby urging the needle cannula outward relative to the housing and shield. Lavi (figures 37-47) and Marshall (abstract, figure 1, and 6-9) discloses a means for allowing the driver to drive the cartridge barrel through the housing following activation of said driver trigger and prior to movement of the stopper through the cartridge barrel, thereby urging the needle cannula outward relative to the housing and shield (abstracts). Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the injection syringe of Chevallier as disclosed by Lavi and/or Marshall to make the safety shield injection syringe automated.

With regard to claims 3-7, 10-15, 35-37, 46-48, 61, 63-64 and 70, Chevallier and Gilbert disclose an injection device according to claims 1 and 9. However, Chevallier may not disclose the driver trigger being coupled to said shield, wherein movement of the shield inwardly with respect to the housing activates the trigger. Marshall discloses (abstract, figure 1, and 6-9) the driver trigger being coupled to said shield, wherein

Art Unit: 3767

movement of the shield inwardly with respect to the housing activates the trigger.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the injection syringe of Chevallier as disclosed by Marshall to make the safety shield injection syringe automated.

With regard to claims 16-18, 53- 57, 60, 22-25, 39-42, 26, 28-31, 49, 65-66, 69, 27, 62, 32-34, 43 and 67-68, Chevallier or Jansen and Gilbert disclose an injection device according to claim 9. However, Chevallier or Jansen may not disclose a set of supports, injector rods, safety tabs, injector cartridge and viewing window. Lavi (shows in figures 37-47 an injection device with a housing (304), a shield (302), a cartridge barrel (204) with a needle cannula (32), a stopper (38), a driver (208), a spring (20), a driver trigger (24), a release mechanism (48+56) and a titration rod (234)) and Marshall (abstract, figure 1, and 6-9) disclose a set of supports, injector rods, safety tabs, injector cartridge and viewing window. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the injection syringe of Chevallier or Jansen as disclosed by Lavi and/or Marshall to make the safety shield injection syringe automated.

Response to Amendment

The present communication responds to the Amendment of 04/28/2008.

By this communication, no claims were amended. The amendments did not add new matter. Claims 1-70 are pending. The rejection(s) are as stated.

Response to Arguments

Applicant's arguments filed 4/28/2008 have been fully considered but they are not persuasive. As seen in the new grounds of rejection, the claims are anticipated and obvious from the prior art.

Applicant's arguments with respect to claims 1-70 have been considered but are moot in view of the new ground(s) of rejection. In response to applicant's arguments of 1, 9, 38, 44, and 45, Gilbert discloses (column 1, lines 20-50) the cannula being disposed within said shield prior to activation of said device and further discloses the syringe is automated.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to applicant's arguments of 2, Gilbert discloses (column 1, lines 20-50) the cannula being disposed within said shield prior to activation of said device and further discloses the syringe is automated.

In response to applicant's arguments of claim 3, Jenson discloses a moving shield.

In response to applicant's arguments of claim 17, about the showing of a driver that includes a set of barrel supports. Bitdinger (US Patent No. 5,478,316 form

Art Unit: 3767

references cited) discloses as early as 1995 the use of a driver (58) system in an injector pen. Marshall (14 and 15), Jenson (20 and 22), Lavi and others all disclose a driver system.

In response to applicant's arguments of claim 18, that the cartridge barrel supports are adapted to detect the end of the barrel and release the driving unit. At least Lavi discloses this feature.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL J. ANDERSON whose telephone number is (571)272-2764. The examiner can normally be reached on M-F 6:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3767

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael J Anderson/
Examiner
Art Unit 3767

MJA
7/16/2008
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767